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Attorneys for Defendant, Rubicon Research Private Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

METACEL PHARMACEUTICALS LLC, *Plaintiff*, v. RUBICON RESEARCH PRIVATE LIMITED, *Defendant*.	C.A. No. 2:21-cv-19463-EP-JRA **DEFENDANT, RUBICON RESEARCH PRIVATE LIMITED'S FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIM**

Defendant Rubicon Research Private Limited ("Rubicon"), by and through their undersigned counsel, respectfully submits their Answer to Plaintiff's Complaint, stating as follows:

RESPONSE PERTAINING TO THE NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 10,610,502 (the "'502 Patent").

RESPONSE: Rubicon admits Plaintiff purports to bring a civil action to assert infringement under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Allegations not expressly admitted are denied.

2. The action relates to the submission of Abbreviated New Drug Application ("ANDA") No. 214445 by Rubicon to the United States Food and Drug Administration ("FDA"), seeking approval for a generic version of Metacel's Ozobax® brand product (5mg/5mL) prior to the expiration of the '502 Patent.

RESPONSE: Rubicon admits Plaintiff purports to bring a civil action to assert infringement of the patent identified in this paragraph under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Rubicon admits to filing ANDA No. 214445. Rubicon denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO THE PARTIES

3. Metacel is a corporation organized and existing under the laws of the State of Georgia, with its principal place of business at 224 East Washington Street, Athens, Georgia 30601.

RESPONSE: Rubicon is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

4. On information and belief, Rubicon is a corporation organized and existing under the laws of India, with its principal place of business at 221 Annexe Building, Goregaon Mulund Link Road Bhandup (West) Mumbai, 400 078 India. Rubicon also maintains a business development and regulatory office in the United States at 666 Plainsboro Road, Suite 605, Plainsboro, New Jersey 08536. Rubicon has authorized Timothy H. Kratz, Kratz & Barry LLP, 1050 Crown Pointe Parkway, Suite 500, Atlanta, GA 30338 to accept service of process on its behalf.

RESPONSE: Rubicon admits that it is an Indian company organized under the laws of India but its principal place of business is at MedOne House, B – 75, Road No. 33, Wagle Estate, Thane West – 400604, Maharashtra, India. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

5. This action for patent infringement arises under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

RESPONSE: Rubicon admits Plaintiff purports to bring a civil action to assert infringement under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Allegations not expressly admitted are denied.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

RESPONSE: Solely for the purpose of this litigation, Rubicon does not challenge subject jurisdiction. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c)(3). *See Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1378 (Fed. Cir. 2020) ("Under the Hatch-Waxman Act, it is 'an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such submission is to obtain approval ... to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.'").

RESPONSE: Solely for the purpose of this litigation, Rubicon does not challenge venue jurisdiction. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

8. This Court has personal jurisdiction over Rubicon based on the presence of its development and regulatory office in Plainsboro, New Jersey, and Rubicon's purposeful availment of the rights and benefits of New Jersey law through its systematic and continuous contacts with the state. Additionally, upon information and belief, Rubicon prepared ANDA No. 214445 at their New Jersey office, thus committing an act of patent infringement within this district. *See* 35 U.S.C. § 271(e)(2).

RESPONSE: Solely for the purpose of this litigation, Rubicon does not challenge personal jurisdiction. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

9. As such, exercising personal jurisdiction over Rubicon in this district is reasonable, given its substantial contacts with the district, and the district's interest in resolving an act of patent infringement that occurred in the State of New Jersey.

RESPONSE: Solely for the purpose of this litigation, Rubicon does not challenge personal jurisdiction. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

10. In the alternative, this Court has personal jurisdiction over Rubicon pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

RESPONSE: Solely for the purpose of this litigation, Rubicon does not challenge personal jurisdiction. Rubicon denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

RESPONSE TO ALLEGATIONS PERTAINING TO THE PATENT-IN-SUIT

11. On April 7, 2020, the United States Patent & Trademark Office issued the '502 Patent, titled "Oral Baclofen Solutions." Metacel is the owner of the '502 Patent and holds the approved NDA No. 208193 for its baclofen oral solution 5mg/5mL sold under the trademark Ozobax®. A copy of the patent at issue is attached hereto as Exhibit A.

RESPONSE: Rubicon is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

12. Pursuant to 21 U.S.C. § 355(b)(1), the '502 Patent is listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations as covering Metacel's Ozobax® brand baclofen oral solution.

RESPONSE: Rubicon is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

RESPONSE TO COUNT I-ALLEGED INFRINGEMENT OF THE '502 PATENT BY RUBICON'S ANDA FOR OZOBAX®

13. Metacel re-alleges the preceding paragraphs as if fully set forth herein.

RESPONSE: Rubicon incorporates each of the preceding paragraphs as if fully set forth herein.

14. An actual controversy exists between the parties as to whether Rubicon's proposed sale of its generic baclofen oral solution infringes on claim 1 of the '502 Patent.

RESPONSE: Denied.

15. By letter dated September 15, 2021, ("Notice Letter"), Rubicon notified Metacel that it submitted ANDA No. 214445 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that ANDA No. 214445 seeks the FDA approval necessary to engage in the commercial manufacture, use, or sale of generic baclofen oral solution (5 mg/5 mL) prior to the expiration of the '502 Patent.

RESPONSE: Rubicon admits to informing Plaintiff of the filing of its ANDA No. 214445 via a letter dated September 15, 2021 ("Notice Letter"). Rubicon denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

16. ANDA No. 214445 includes a Paragraph IV Certification that the claims of the '502 Patent are invalid, unenforceable, and/or not infringed.

RESPONSE: Admitted.

17. On information and belief, the Notice Letter, purportedly sent to Metacel via overnight mail, was delivered no earlier than September 16, 2021, although was not received until September 20, 2021.

RESPONSE: Rubicon is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

18. The Notice Letter was subsequently received by Metacel, and Metacel initiated this action within 45 days of the date of receipt of the Notice Letter.

RESPONSE: Rubicon is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies the same.

19. Rubicon has actual knowledge of the '502 Patent, as shown by the Notice Letter.

RESPONSE: Admitted.

20. Rubicon has not yet provided the full details of its composition and generic version of Metacel's Ozobax® product. On information and belief, Rubicon's proposed generic version of Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL), if approved and marketed, will infringe, either literally or under the doctrine of equivalents, claims 1 and 2 of the '502 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

RESPONSE: Denied.

21. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Rubicon has infringed claims 1 and 2 of the '502 Patent by submitting to FDA, or causing to be submitted to the FDA, ANDA No. 214445 and seeking approval to manufacture, use, or sell Rubicon's proposed generic version of Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL) before the expiration date of the '502 Patent.

RESPONSE: Denied.

22. On information and belief, the product described in ANDA No. 214445 would infringe, either literally or under the doctrine of equivalents, claims 1 and 2 of the '502 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

23. On information and belief, physicians, pharmacists, and/or patients will directly infringe claims 1 and 2 of the '502 Patent by use of the generic version of Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL) upon approval.

RESPONSE: Denied.

24. On information and belief, upon approval, Rubicon will take active steps to encourage the use of Rubicon's generic version of Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL) by physicians, pharmacists, and/or patients with the knowledge and intent that Rubicon's generic product will be used in a manner that infringes claims 1 and 2 of the '502 Patent for the pecuniary benefit of Rubicon.

RESPONSE: Denied.

25. On information and belief, upon approval, Rubicon will either directly or indirectly promote substitution of its generic baclofen oral solution for Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL), including through pharmaceutical drug databases like First DataBank and Medi-Span, drug formularies, insurers, third-party benefit managers, and government healthcare programs like Medicare, which will cause conversion of at least a portion of the market for Metacel's Ozobax® brand baclofen oral solution (5 mg/5 mL) to Rubicon's generic oral baclofen solution.

RESPONSE: Denied.

26. Pursuant to 21 C.F.R. § 314.94, Rubicon specifically intends its generic baclofen product to be used according to its proposed labeling in a manner that infringes claims 1 and 2 of the '502 Patent. On information and belief, Rubicon will thus induce the infringement of claims 1 and 2 of the '502 Patent.

RESPONSE: Denied.

27. On information and belief, if the FDA approves ANDA No. 214445, Rubicon will sell or offer to sell its proposed generic product specifically labeled for use in practicing claims 1 and 2 of the '502 Patent, wherein Rubicon's proposed generic product will be used in a manner that infringes the claimed inventions. Further, Rubicon knows that it will manufacture or direct the manufacture of the composition utilized in claims 1 and 2 of the '502 Patent. Also, physicians will prescribe, pharmacists will formulate and distribute, and patients will use Rubicon's proposed generic product in accordance with the instructions and/or label provided by Rubicon in practicing claims 1 and 2 of the '502 Patent.

RESPONSE: Denied.

28. Rubicon's generic baclofen oral solution does not constitute staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

29. Rubicon's proposed generic baclofen oral solution product is specifically designed for use in a manner that infringes on claims 1 and 2 of the '502 Patent. On information and belief, Rubicon will thus contribute to the infringement of claims 1 and 2 of the '502 Patent.

RESPONSE: Denied.

30. On information and belief, the actions described in this Complaint relating to Rubicon's ANDA No. 214445 were conducted by, and for the benefit of, Rubicon.

RESPONSE: Denied.

31. Metacel will be irreparably harmed by Rubicon's infringing activities unless those activities are enjoined by this Court. Metacel does not have an adequate remedy at law.

RESPONSE: Denied.

32. This case is exceptional, such that Metacel is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

RESPONSE: Denied.

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Rubicon are hereby denied. Having answered Plaintiff's complaint, Rubicon denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Rubicon asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Rubicon's ANDA No. 214445 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patent-in-suit.

SECOND SEPARATE DEFENSE

Each of the claims of each of the patent-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or for satisfying other bases (including judicially created bases) for invalidation or unenforceability.

THIRD SEPARATE DEFENSE

Each of the claims of each of the patent-in-suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102, 103, for example, for at least the reasons set forth in Rubicon's Notice Letter.

FOURTH SEPARATE DEFENSE

Each of the claims of each of the patent-in-suit is invalid pursuant to 35 U.S.C. § 112, due to for example, indefiniteness, lack of enablement and/or written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patent-in-suit, Plaintiff is estopped from maintaining that any valid or enforceable claim of the patent-in-suit is infringed by the product that is the subject of Rubicon's ANDA No. 214445.

SIXTH SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Rubicon hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the patent-in-suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

DEFENDANT RUBICON'S COUNTERCLAIM

Pursuant to Rule 13 of the Federal Rules of Civil Procedure Defendant, Rubicon Research Private Limited (herein, "Rubicon") by and through its undersigned attorneys, and as for its Counterclaim against Plaintiff, Metacel Pharmaceuticals LLC (herein, "Metacel") here by states the following:

1. Rubicon repeats and incorporates by reference each of the foregoing paragraphs of Rubicon's Answer and Affirmative Defenses to the Complaint.

2. This is an action to recover damages for Metacel's violations of Section 2 of the Sherman Act. Specifically, Rubicon asserts that Metacel has maintained its monopoly power granted to it from the issuance of U.S. Patent No. 10,610,502 ("the '502 patent" or the "patent-in-suit") through sham litigation such that Metacel has lost its immunity from civil action for Sherman Act violations and Rubicon is entitled to recover for the anti-trust injuries resulting therefrom.

THE PARTIES

3. Counterclaim-Plaintiff, Rubicon, is a corporation organized and existing under the laws of India, having a place of business at MedOne House, B – 75, Road No. 33, Wagle Estate, Thane West – 400604, Maharashtra, India.

4. Upon information and belief based on Plaintiff's own Complaint, Metacel is a corporation organized and existing under the laws of the State of Georgia, with its principal place of business at 224 East Washington Street, Athens, Georgia 30601.

5. On information and belief, based on Plaintiff's own Complaint, Metacel is the current owner and assignee of the '502 patent listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Metacel's Ozobax®, and that is the Patent-In-Suit.

JURISDICTION

6. This Court has subject matter jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), and 1367, based on an actual controversy between Counterclaim-Plaintiff, on the one hand, and the Counterclaim-Defendant on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

7. This court has personal jurisdiction over Metacel based, inter alia, on the filing of this lawsuit in this jurisdiction and because Metacel is doing business in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

HATCH-WAXMAN ACT BACKGROUND

9. The Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, establish the rules under which FDA considers whether to approve brand-name and generic pharmaceutical drugs. In 1984, the Hatch-Waxman Act was passed to amend certain aspects of this regulatory structure with a central aim of getting "generic drugs into the hands of patients at reasonable prices – fast." *In re Barr Labs.*, 930 F. 2d 72, 76 (D.C. Cir. 1991).

10. Under the Hatch-Waxman Act, an abbreviated approval pathway for FDA's consideration of generic drugs was created to "speed the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). This pathway authorizes the approval of generic drugs based upon the submission of an Abbreviated New Drug Application ("ANDA").

11. The Hatch-Waxman Act balances the public interest in speedier entry of generic competition with the public interest in protecting the legitimate use of the patent system and thereby fostering innovation in the pharmaceutical industry. In recognizing the value of legitimate patents in incentivizing innovation, Congress created a process to postpone generic entry to afford time for early resolution of patent disputes. *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394-6 (3d Cir. 2015). Under this system, FDA requires NDA holders to disclose the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2). Generic applications are then required to address each listed patent by certifying that they will wait for the patent to expire to receive final FDA approval, or by filing a "Paragraph IV" certification challenging the patent as invalid, unenforceable, or not infringed by the proposed generic product.

12. The Hatch-Waxman Act makes the submission of an ANDA with a Paragraph IV certification a "technical" act of infringement in order to establish standing for streamlined resolution of possible patent infringement issues that would arise from the market entry of the ANDA product. The Act gives patentees a strong incentive to file suit, if at all, within 45 days of receiving a Paragraph IV challenge. If the patentee files suit within that window, FDA imposes a 30-month stay on any approval of the generic application so long as the patent litigation remains

pending at the District Court during that time. Thus, in a legitimate patent infringement dispute, patent holders are protected by giving an opportunity to assert legitimate claims before a generic is approved and ANDA filers are protected by providing them with certainty with respect to their potential litigation risk, all before the generic product is launched.

13. In order to incentivize generic companies to submit ANDAs as early as possible, the Hatch-Waxman Act offers a regulatory reward to the first generic manufacturer to challenge invalidity or non-infringement of the listed patents with a 180-day period of generic marketing exclusivity.

14. Accordingly, the entire framework of the Hatch-Waxman Act balances the legitimate patent interests of the branded company with the interest in creating competition through early generic entry. If used properly, and not abused, this structure serves the underlying purpose of getting "generic drugs into the hands of patients at reasonable prices – fast."

OZOBAX®

15. Upon information and belief, Metacel's brand name product, Ozobax®, was approved by FDA as NDA 208193 on September 18, 2019. Ozobax® is an oral solution product containing baclofen as the active ingredient in 5mg/5ml strength,

16. Upon information and belief, on April 7, 2020, the U.S. Patent and Trademark Office ("USPTO") issued the '502 patent. On information and belief, a true and correct copy of the '502 Patent is attached to Plaintiff's Complaint at Exhibit A.

17. Upon information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Metacel caused the FDA to list the patent-in-suit in the Orange Book in connection with NDA No. 208193.

18. By maintaining the listing of the patent-in-suit in the Orange Book, Metacel represents to the world that the patent-in-suit could reasonably be asserted if a person not licensed

by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product or a bioequivalent baclofen oral solution product before the expiration of the patent-in-suit.

19. As such, Metacel has created a relevant market (baclofen oral solution products) to which Metacel possesses monopoly power within the meaning of Section 2 of the Sherman Act.

RUBICON'S ABBREVIATED NEW DRUG APPLICATION (ANDA)

20. Rubicon filed ANDA No. 214445 ("ANDA") with the FDA seeking approval to market a baclofen oral solution 5mg/5ml, intended to be a bioequivalent version of Ozobax®. Rubicon's Paragraph IV Certification Letter (the "Notice Letter") concerning the patent-in-suit certified that to the best of Rubicon's knowledge all of the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the product described in Rubicon's ANDA, and that Rubicon was seeking approval of its ANDA prior to the expiration of the patent-in-suit.

21. Rubicon's ANDA is the first ANDA to be filed seeking FDA approval to market a product that would compete with Metacel's Ozobax® product.

METACEL'S LAWSUIT

22. On October 29, 2021, Metacel filed an infringement action ("Metacel's suit") under Title 35, United States Code, Sections 100 *et seq*., asserting the patent-in-suit against Rubicon.

23. Metacel's suit was filed within 45 days of receipt of the Notice Letter, such that Rubicon's ANDA is subject to a regulatory stay of final approval for a 30-month period from

receipt of the Notice Letter so long as Metacel's suit is maintained during that period. The regulatory stay expires on March 16, 2024.

24. Rubicon timely filed its Answer on January 21, 2022, and simultaneously served on Metacel a copy of its ANDA.

25. From that point forward, Metacel's suit was objectively baseless in that no reasonable litigant could realistically expect success on the merits.

26. Specifically, the claims of the '502 patent are method claims that require, as independent claim limitations, the following steps arranged in chronological order: (a) a determination that the oral solution is below a threshold level for a specific impurity ("the impurity limitation"); (b) subsequent storage of the oral solution in refrigerated conditions ("the refrigeration limitation"); and (c) administration of the oral solution containing at least the active ingredient and a buffer comprising citric acid, a salt of citric acid, or any combination thereof ("the buffer limitation").

27. Rubicon has not and does not make a determination regarding the impurity specified in the impurity limitation.

28. Rubicon's ANDA product does not require a determination regarding the impurity specified in the impurity limitation.

29. Rubicon's ANDA label does not describe or direct anyone reading the label or using Rubicon's ANDA product to undertake any determination regarding the impurity specified in the impurity limitation.

30. Rubicon does not refrigerate the product to be sold under the ANDA.

31. Rubicon's ANDA product does not require refrigeration.

32. Rubicon's ANDA product label does not instruct storing Rubicon's ANDA product in refrigerated storage conditions.

33. Rubicon's ANDA product does not contain a buffer.

34. Rubicon's ANDA product does not contain citric acid.

35. Metacel knew that it would have to prove each of these limitations and that failure to do so with respect to any of them would result in a judgment of non-infringement.

36. Rubicon's ANDA discloses that none of these steps are met by Rubicon's ANDA product or the proposed label for Rubicon's ANDA product. No reasonable litigant could realistically expect to succeed in asserting infringement of the '502 patent against Rubicon's ANDA product. Accordingly, Metacel knew that its suit was objectively baseless at least from the time it received Rubicon's ANDA.

37. On July 27, 2022, Rubicon filed its Motion for Leave to File Motion for Summary Judgment of Non-Infringement, and included its motion for summary judgment and supporting documents as Exhibits to the Motion for Leave. Rubicon's motion for summary judgment disclosed to Metacel on July 27, 2022, detail precisely how Rubicon's ANDA product and the proposed label for Rubicon's ANDA product do not meet any of the three limitations described above either directly, indirectly, or under the doctrine of equivalents.

38. On February 10, 2023, Rubicon filed its Motion for Summary Judgment, and supporting papers. This Motion is fully briefed and pending before the Court.

39. Despite Metacel's objectively baseless suit, Metacel has maintained the litigation in an attempt to directly interfere with Rubicon's business relationships, using this litigation as an anticompetitive weapon against Rubicon. Specifically, Metacel is using the pendency of this

litigation to prevent Rubicon from competing in the baclofen oral solution market, with knowledge and the specific intent to use this litigation as a competitive tool.

40. Upon information and belief, during the pendency of this wrongful lawsuit, Metacel began marketing its own "authorized generic" version of its Ozobax oral solution product, gaining yet another improper monopoly, this time on the generic market, and eroding the potential generic market for Rubicon's product, notwithstanding Rubicon's superior product, which does not require refrigeration, requiring additional outlay of capital to be budgeted for marketing purposes by Rubicon to distinguish the products to consumers.

41. Metacel's maintenance of this suit is a sham as objectively shown by Metacel's conduct. Metacel's conduct thus shows it possessed, and still possesses, the specific intent to monopolize the market for baclofen oral solution.

RUBICON'S ANDA RECEIVES TENTATIVE APPROVAL

42. On March 13, 2023, Rubicon was granted Tentative Approval of its ANDA by FDA, representing a determination by FDA that Rubicon's ANDA product is bioequivalent and therapeutically equivalent to Metacel's Ozabox Oral Solution product.

43. In FDA's approval letter, it stated that final approval could not be granted due to the "patent issue noted below", referring to the existence of Metacel's suit. FDA expressly stated that final approval could not be granted for Rubicon's ANDA product until the court decides that the '502 patent is not infringed or until expiration of the 30-month stay.

44. Accordingly, Rubicon has suffered an antitrust injury within the meaning of Section 2 of the Sherman Act in that Rubicon has suffered an injury-in-fact by being wrongfully kept off the market for baclofen oral solution, which is directly and proximately caused by Metacel

maintaining this sham litigation in violation of the Sherman Act and which is the type of injury contemplated by the Sherman Act.

THE RELEVANT MARKET

45. The relevant geographic market is the United States. The FDA's regulatory process for approving drugs for sale in the United States, and the fact that such sales occur on a nationwide basis establishes the boundaries of the geographic market.

46. The relevant product market in which to assess the anticompetitive effect of Metacel's conduct is the market for baclofen oral solution for its approved indication(s), which include only Metacel's Oxobax and Metacel's own generic version of Ozobax during the relevant time period.

47. While there are other baclofen products available, aside from Metacel's own authorized generic product, the other baclofen products are not market substitutes for Ozobax® and are not interchangeable prescription substitutes. Accordingly, the Ozobax® market, including now its generic market, is a distinct product market that Metacel has created and improperly maintained through its anticompetitive conduct set forth herein.

48. Metacel has monopoly power in the relevant market, with 100% market share, control over pricing and output of products and no competition.

METACEL'S ANTICOMPETITIVE CONDUCT

49. Metacel improperly maintains its monopoly through anticompetitive conduct by maintaining this sham litigation.

50. But for this anticompetitive conduct, Rubicon would have been permitted entry into the relevant market as of March 13, 2023.

51. Metacel's anticompetitive conduct, which includes securing a monopoly on the generic market, injured Rubicon by excluding Rubicon from the relevant market from March 13, 2023, and continues to injure Rubicon by excluding Rubicon from the relevant market and eroding Rubicon's potential generic market share.

52. As a direct and proximate result of Metacel's anticompetitive conduct, Rubicon has lost and continues to lose significant sales that it would have made as the first generic entrant in the relevant market. The harms to Rubicon as a result of Metacel's anticompetitive conduct are continuing and will have long-term effects in the form of lost sales and business opportunities.

53. These injuries to Rubicon constitute antitrust injury.

54. Each day Metacel maintains a monopoly over the Ozobax and generic Ozobax market consumers are harmed by the lack of competition and low-cost alternatives to the Ozobax product, including Rubicon's superior ANDA product, which does not require refrigeration.

COUNT I – VIOLATION OF SECTION 2 OF THE SHERMAN ACT

55. Rubicon repeats and incorporates by reference the allegations of paragraphs 1 – 54 as if fully set forth herein.

56. Metacel possessed and possesses monopoly power in the relevant market.

57. Metacel engaged in and continues to engage in anticompetitive conduct to restrain trade and monopolize both the Ozobax market and the generic market for its own Ozobax product by continuing and maintaining this objectively baseless lawsuit with the specific intent of preventing Rubicon from obtaining final FDA approval for its ANDA and selling its superior baclofen product to U.S. consumers.

58. Metacel acted with the specific intent to improperly monopolize and cause harm.

59. Metacel's actions have unreasonably restrained trade in the relevant market.

60. Metacel's actions have occurred in, has had, and continues to have a substantial effect on interstate commerce.

61. As a direct and proximate cause of Metacel's exclusionary and anticompetitive conduct, Rubicon has been injured and has sustained damages.

62. As a direct and proximate cause of Metacel's exclusionary and anticompetitive conduct, Rubicon continues to be injured and will continue to sustain damages in the future.

63. The injuries to Rubicon constitute antitrust injuries to which it is entitled to recover for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2.

PRAYER FOR RELIEF

WHEREFORE, Rubicon respectfully requests that the Court enter judgment in its favor and against Metacel as follows:

a. Denying and dismissing Plaintiff's Complaint with prejudice.

b. Declaring that the claims of the patent-in-suit are invalid;

c. Declaring that the claims of the patent-in-suit are not, and will not be, infringed by Counterclaim-Plaintiff's manufacture, use, sale, offer for sale, or importation of the baclofen product that is the subject of Rubicon's ANDA;

d. Declaring that the claims of the patent-in-suit are unenforceable;

e. Declaring that the Plaintiff is not entitled to damages for any alleged infringement by Defendant for the patent-in-suit;

f. Preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from utilizing the patent-in-suit to block, hamper, hinder or obstruct FDA approval of Counterclaim-Plaintiff's baclofen product;

g. Permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce the Patent-in-Suit against the Counterclaim-Plaintiff or anyone in privity with the Counterclaim-Plaintiff;

h. Declaring this case "exceptional" and awarding the Counterclaim-Plaintiff their attorneys' fees and costs pursuant to 35 U.S.C. § 285, the inherent power of this Court, or otherwise;

i. Awarding Rubicon its actual damages, treble damages, prejudgment interest, costs and attorney fees, and other such further relief as may be available, under Section 2 of the Sherman Act; and

j. Awarding any other such and further relief as is just and proper.

Dated: August 8, 2023

Respectfully submitted,

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